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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. VINOD CHANDRASHEKM PATWARDHAN, Defendant.	Case No. ED CR 08-00172 VAP **[Motion filed on May 29, 2009]** **ORDER DENYING MOTION FOR JUDGMENT OF ACQUITTAL AND/OR NEW TRIAL**

Defendant's Motion for Judgment of Acquittal and/or New Trial came before the Court for hearing on June 29, 2009. After reviewing and considering all papers filed in support of, and in opposition to, the Motion, as well as the arguments advanced by counsel at the hearing, the Court DENIES the Motion.

I. BACKGROUND

Defendant Vinod Patwardhan was tried before a jury on the first six counts in the Second Superseding Indictment in this Court from April 28, 2009 through May 7, 2009; the jury returned a guilty verdict on all six counts on May 8, 2009.[1]

After the Government rested its case, Defendant brought a Motion for Acquittal pursuant to Rule 29 of the Federal Rules of Criminal Procedure. The Court denied the Motion on May 8, 2009, before the jury returned its verdict.

[1] Count One charged Defendant with Conspiracy to Introduce into Interstate Commerce Drugs That Are Misbranded, in Violation of Title 21 U.S.C. §§ 331(a), 333(a)(2), 352(c) & 352 (f)(1) (Violation of 18 U.S.C. § 371); Count Two charged him with Introducing and Delivering Misbranding Drugs into Interstate Commerce, Specifically 23 Vials of Farmorubicina, 50 MG (Violation of 21 U.S.C. §§ 331(a), 333(a)(2), 352(c) & 352(f)(1)); Count Three Charged him with Introducing and Delivering Misbranded Drugs into Interstate Commerce, Specifically 100 Vials Of Docetax, 80 MG (Violation of 21 U.S.C. §§ 331(a), 333(a)(2), 352(c) & 352(f)(1)); Counts Four, Five and Six charged Fraudulently and Knowingly Importing or Causing the Importation of Drugs from India into the United States (violation of 18 U.S.C. § 545); and Counts Seven and Eight sought forfeiture of Defendant's assets.

On May 29, 2009, Defendant filed a "Motion for Judgment of Acquittal and/or New Trial."[2] The Government filed Opposition on June 15, 2009. Defendant filed a Reply on June 22, 2009.

II. MOTION FOR NEW TRIAL

Defendant brings his Motion for New Trial on the following grounds: (1) the Court's mid-trial decision regarding the admissibility of Patrick Egan's testimony resulted in undue prejudice to Defendant; and (2) Agent Leitner's improper comment violated Defendant's Fifth Amendment right. (See Mot. at 8-17, 26-28.)

A. Legal Standard

Rule 33(a) of the Federal Rules of Criminal Procedure ("Rule 33(a)") provides that "[u]pon the defendant's motion, the court may vacate any judgment and grant a new trial if the interest of justice so requires." A motion for a new trial is granted at the discretion of the trial court and only in "exceptional cases in which the evidence preponderates heavily against the verdict." United States v. Pimentel, 654 F.2d 538, 545 (9th Cir. 1981).

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[2] The Motion was timely filed because the Court granted Defendant an extension of time, beyond the seven day deadlines set forth in Federal Rules of Criminal Procedure 29(c)(1) (motion for acquittal) and 33(b)(2)(motion for new trial).

A trial court may sustain a verdict if "'viewing the evidence in the light most favorable to the prosecution, *any* rational trier of fact could have found the essential elements of the crime beyond a reasonable doubt.'" United States v. Lyons, 454 F.3d 968, 971 (9th Cir. 2006) (emphasis in original) (quoting Jackson v. Virginia, 443 U.S. 307, 319 (1979).

B. Discussion

1. Admissibility of Patrick Egan's Testimony

At a pretrial hearing, the Court denied the Government's Motion in Limine to exclude defense expert Patrick Egan from testifying. (See April 22, 2009 Order.) The defense sought to have Mr. Egan testify to the following: (1) various cities and states imported foreign-labeled drugs; (2) the Attorney General can create exemptions for travelers carrying drugs with them when entering the country; (3) the Food and Drug Administration ("FDA") and Drug and Enforcement Agency ("DEA") have issued public statements regarding the prescription drugs that travelers can bring into the country; (4) confusion among the general public regarding the importation of prescription drugs for personal use and the FDA and DEA have called for greater clarity on the issue; and (5) the FDA's creation of policies for its inspectors to follow with respect to the importation by

travelers of small amounts of prescription drugs. (Id. at 3.)

In its Motion in Limine ruling, the Court found Mr. Egan's proffered testimony would be relevant to the following issues: (1) whether the Defendant lacked intent to defraud; and (2) the purported reasonableness of Defendant's belief that he acted lawfully. (Id.)

On May 3, 2009, the Government brought a "Motion for Reconsideration of the Court's Prior Order Permitting Testimony of Defendant's Expert Witness Patrick Egan," which the Defendant opposed. Outside the presence of the jury, the Court heard argument on the Motion and ruled that Mr. Egan could not testify until the defense laid sufficient foundation, i.e., through the Defendant's own testimony or otherwise, that he was confused about the FDA's prescription drug importation policy and about the wrongfulness of his actions. The defense objected that this constituted a change in the Court's earlier ruling, and that circumstantial evidence regarding the manner of Defendant's importation of the drugs sufficed as foundation for the expert's testimony.

As it stated on the record during the hearing, the Court's ruling during trial on the admissibility of Egan's testimony was not a change from its prior ruling.

Rather, it simply reiterated the rule that any evidence must be supported with sufficient foundation before it may be admitted and published to the jury, whether testimonial or documentary. See Fed. R. Evid. 402; LuMetta v. U.S. Robotics, Inc., 824, F.2d 768, 771 (9th Cir. 1987). The Court found the evidence cited by defense counsel did not provide sufficient foundation for Egan's testimony; there was no connection between the proffered testimony regarding general confusion of the public as to the FDA's importation policy of prescription drugs for personal use and the Defendant's acts of importing, or directing others to import, prescription drugs to distribute to his patients and not for personal use. Accordingly, the Court ruled, lacking the requisite foundation (in the form of Defendant's testimony, for example), that the Defendant held the belief he was acting lawfully, consistent with the general public's confusion regarding the legality of importing prescription drugs for personal use, Egan's testimony was inadmissible.

In the Motion for a New Trial, Defendant argues the Court's ruling entitles him to a new trial for two reasons: (1) the Court was incorrect in ruling the Defendant must testify before Mr. Egan's expert testimony could be introduced; and (2) Defendant was prejudiced unduly because defense counsel, relying on the Court's

Motion in Limine ruling, previewed Mr. Egan's testimony to the jury during his opening statement but was unable to deliver on his promise that Egan would testify. (See Mot. at 8-9.)

As to his first reason, Defendant argues United States v. Frantz, 2004 WL 5642909 (C.D. Cal. April 23, 2004), authored by the Honorable Margaret M. Morrow of this Court, shows the impropriety of the Court's requirement that the Defendant testify before Mr. Egan could testify. The Court notes Defendant opposed the Government's Motion for Reconsideration by arguing the applicability of this case; the Court previously distinguished this case at the hearing on the Motion for Reconsideration. Frantz is a tax fraud case with little factual similarity to this case. Although the Frantz Court did not require the defendant to testify to lay sufficient foundation for his expert's testimony, it held the defense could lay sufficient foundation through other circumstantial evidence.

Here, the defense proffered the circumstantial evidence of Defendant's belief as to the legality of his actions, i.e., Defendant's own testimony about his beliefs, to satisfy Federal Rule of Evidence 402's foundation requirements for Mr. Egan's testimony. The Court abides by its ruling on this issue for the reasons

stated above and on the record during the hearing on the Motion to Reconsider.

Defendant's second basis, that he suffered unfair prejudice because his lawyer described Egan's testimony during his opening statements but the Court barred him from presenting the witness's testimony, lacks merit as well. At the hearing on this issue during trial, the defense framed this argument as an objection under Federal Rule of Evidence 403, contending Defendant would be unfairly prejudiced if not allowed to present Egan's testimony.

Rule 403, however, only allows the exclusion of relevant evidence when the danger of, inter alia, unfair prejudice outweighs its probative value. The defense here was not seeking to *exclude* evidence, but rather *admit* it. As the Court pointed out at the hearing, balancing the interests at stake here, i.e., (1) the purported prejudice to Defendant because he was unable to offer the testimony of his expert witness after describing it to the jury during opening statement, balanced against (2) the impropriety of permitting a witness whose testimony lacked proper foundation to testify, did not favor the defense.

Defendant next argues his counsel's promise in opening statement of Egan's testimony, and subsequent inability to deliver it, constitutes grounds for a new trial. (See Mot. at 13 ("Courts have repeatedly held that a defense attorney's failure to present the promised testimony of an important witness constitutes conduct that is so profoundly prejudicial to the criminal defendant that it warrants reversal or vacation of a conviction.").) In support of his argument, Defendant relies on several cases, to no avail. (See Mot. at 13-17 (citing Ouber v. Guarino, 293 F.3d 19 (1st Cir. 2002); States v. Washington, 219 F.3d 620 (7th Cir. 2000); Harris v. Reed, 894 F.2d 871 (7th Cir. 1990); Anderson v. Butler, 858 F.2d 16 (1st Cir. 1998); United States v. Gonzalez-Maldonado, 115 F.3d 9 (1st Cir. 1997)).)

First, most of Defendant's cited cases arise in the context of habeas corpus petitions granted because of ineffective assistance of trial counsel, a completely different legal question than that posed here. See, e.g., Ouber, 293 F.3d at 33-34; Washington, 219 F.3d at 634; Harris, 894 F.2d at 879; Anderson, 858 F.2d at 17. Furthermore, most of Defendant's cases are distinguishable factually; there, the defense counsel failed, either out of incompetence or negligence, to call "key" witnesses they described during opening statements to the jury. Id. Defense counsel here did not fail to

call Dr. Egan; he attempted to do so but was not allowed, as the evidentiary requirements for the witness's testimony had not been satisfied.

Defendant relies in particular on the First Circuit's decision in Gonzalez-Maldonado. That case, too, is distinguishable from ours. There, the district court stated it would allow an expert to testify about the mental illness of the defendant's co-conspirator, Julio Robles-Torres ("Robles"), who the court had found incompetent to testify at trial. 115 F.3d at 14. In lieu of Robles's testimony, the Government planned to introduce taped conversations between the defendant and Robles in its case-in-chief as evidence of the conspiracy. Id. at 13-14. The Robles tapes constituted key evidence of the defendants' guilt in the government's case. Id. at 16.

During opening statements, defense counsel and counsel for the government mentioned anticipated testimony regarding Robles's mental state. Id. at 14. Specifically, defense counsel told the jury:

> "The expert selected by this Court, Dr. Fumero, selected by this Court, will come here, will sit there and will testify that during this conspiracy ... Mr. Julio Robles-Torres was mentally insane. Therefore, you cannot trust him. You cannot put much

> attention to what he's saying because he exaggerates."

Id. After the government rested its case, the district court "reconsidered its earlier decision and decided that Dr. Fumero would not be allowed to testify because the testimony would only go to the issue of Robles'[s] competency as a witness, which is a question for the court ...." Id.

On appeal, the First Circuit found it reversed the conviction. It held Dr. Fumero's testimony admissible and relevant to Robles's credibility, and the defendant had suffered prejudice as a matter of law when the district court reconsidered its ruling on the expert's ability to testify after both counsel mentioned his testimony in their opening statements. Id. at 15-16. Emphasizing the critical nature of Dr. Fumero's testimony, the First Circuit explained:

> "A defendant's opening statement prepares the jury to hear his case. If the defense fails to produce promised expert testimony that is critical to the defense strategy, a danger arises that the jury will presume that the expert is unwilling to testify and the defense is flawed. That the defendant should suffer this presumption because he relied on a prior ruling of the trial court that the same court later reversed, rather than because of poor judgment on the

> part of his own counsel, in no way changes the fact that the presumption formed in the minds of the jury is prejudicial.... [W]e find that promising to admit this important evidence and then failing to produce it is prejudicial as a matter of law in the circumstances of this case.... [W]e find that denying defendants the opportunity to have Dr. Fumero testify, in light of the fact that the court's decision on the matter led defense counsel, in their opening remarks, to promise the expert's testimony to the jury, was reversible error."

Id. at 15 (emphasis added).

An examination of the record here reveals that by contrast defense counsel only briefly mentioned Patrick Egan and his anticipated testimony during opening statement, as part of what he called the "general background." His description consumed but eleven lines of the twenty-three transcribed pages of the defense's opening statement:

> "You will hear from an expert on this issue [of the FDA's Personal Importation Policy], a man by the name of Patrick Egan. Mr. Egan is a lawyer and he has a lot of experience dealing with this area of importations of drugs and unapproved labeling and things like that. He's testified in the United States Congress about it. And Mr. Egan will testify,

he will tell you that various government agencies have complained that there's a lot of confusion out there in the public, among the public, about whether it's permitted for a traveler to bring medicine and under what circumstances it is permitted for a traveler to bring medicine from a foreign country into the United States."

Before and after this short reference to Dr. Egan, Defendant's lawyer covered many other subjects in his opening statement, including:

- Defendant's national origin, medical training, and years of experience as a doctor;
- Some details about Defendant's medical practice in Upland, California and his specialization in internal medicine and oncology;
- Defendant's dedication to his patients and his staff;
- Defendant's efforts to stay current in his profession;
- Defendant's general record-keeping practice in his office;
- Defendant's frequent travel to India to visit his parents and his purchase of drugs there to bring back to the U.S. to use in his practice;

- Jessica Young's expected testimony about importing drugs from Honduras at the direction of Defendant;
- Defendant's procedure for stocking the drugs in his office, administering them to his patients, and generating invoices for the drugs he imported;
- Defendant's administration of the drugs he imported to his patients;
- An overview of the charges against Defendant;
- The time line of events charged in the Indictment;
- A description of the elements of "acting with intent to defraud or mislead";
- The defense's contention that the charges were about the labeling on the drugs, not the drugs themselves;
- The appearance of the labeling on some of the drugs imported by Defendant;
- Defendant's belief that his actions were legal;
- Defendant's admission that he imported drugs into the United States;
- The manner in which Defendant imported the drugs in his luggage;
- Specific instances of Defendant's interaction with Customs agents;

- Defendant's interaction with Customs agents on April 4, 2002;
- Defendant's interaction with Customs on April 3, 2005;
- The expected testimony of United States Customs Service Agent Cuevas, who interacted with Defendant on April 3, 2005;
- The FDA policy regarding importing drugs for personal use;
- United States Customs agents' discretion when enforcing the FDA policy;
- The policy of the United States Customs Service on retention of declaration forms filled out by travelers;
- The difference between brand names for drugs and their corresponding chemical names;
- Medicare's reimbursement policy and practice for drugs administered by doctors to their patients; and
- Defendant's failure to destroy documents or the imported drugs before or after the FDA searched his office on July 30, 2008.

In other words, viewing the reference to Dr. Egan's testimony in the context of the entire opening statement, it was a very brief mention amongst dozens of other subjects. In contrast to Gonzalez-Maldonado, this is not

a case where the government was able to present its critical witness's testimony through taped evidence but the defendant was unable to cross-examine him or call a witness to question his credibility. Instead, the defense seeks admission of expert testimony unsupported by foundation. In Gonzalez-Maldonado, Dr. Fumero's testimony weighed on the credibility of Robles's recorded statements; here, Egan's testimony could not show the reasonableness of Defendant's actions, as Defendant argues, because there was no link between the reasonableness of a mistaken belief about the FDA's personal importation policy for prescription drugs and Defendant's actions in this case.

Furthermore, as the Government points out in its Opposition, the Court's rulings on Motions in Limine are not binding on the Court throughout the trial. (See Opp'n at 8 (citing Ohler v. United States, 529 U.S. 753, 758 n. 3 (2000) and Luce v. United States, 469 U.S. 38, 41-42 (1984)). As the Supreme Court noted in Luce, where, as here, the defendant chose not to testify at trial:

> "Any possible harm flowing from a district court's *in limine* ruling permitting impeachment by a prior conviction is wholly speculative. The ruling is subject to change when the case unfolds, particularly if the actual testimony differs from what was

contained in the defendant's proffer. Indeed even if nothing unexpected happens at trial, the district judge is free, in the exercise of sound judicial discretion, to alter a previous *in limine* ruling." Id.

Finally, the purported prejudice to Defendant by being unable to deliver his expert witness was cured by the following: (1) the Court gave the Ninth Circuit Model Criminal Jury Instruction No. 3.7 to the jury, explaining that statements by counsel are not evidence; and (2) the Court barred the Government from arguing defense counsel "broke its promise" by failing to introduce Egan's testimony and, in fact, no witness or lawyer mentioned Egan in front of the jury after defense counsel made the aforementioned reference during his opening statement.

Accordingly, the Court's decision to bar Dr. Egan from testifying does not constitute sufficient grounds for the Court to grant Defendant's Motion for New Trial.

2. Agent Leitner's Testimony

Agent Leitner, a Special Agent with the FDA Office of Criminal Investigations, testified during the Government's case about an interview he conducted of Dr. Patwardhan. On direct examination, the agent testified that when interviewed during the search of his office

premises, Defendant said "words to the effect that . . . I am less than a man or I'm not a man." When asked on redirect examination why he remembered that statement by Defendant, Agent Leitner testified as follows:

> Answer: It was, I mean, the defendant is sitting right there. He knows full well that he made that comment and it was stated. We did talk about that.

The defense objected immediately; the Court sustained the objection and instructed the jury to disregard the agent's answer. At the end of the trial when the Court instructed the jury on the applicable law, the Court gave the Ninth Circuit Model Criminal Jury Instruction No. 3.3 about Defendant's decision not to testify: "A defendant in a criminal case has a constitutional right not to testify. No presumption of guilt may be raised, and no inference of any kind may be drawn, from the fact that the defendant did not testify."

Defendant now argues Agent Leitner's statement violated his Fifth Amendment right not to testify at trial, i.e., that the "Fifth Amendment prohibits the prosecution from commenting on a defendant's decision not to testify." (See Mot. at 26 (citing Lincoln v. Sunn, 807 F.2d 805, 809 (9th Cir. 1987)).) Defendant argues Agent Leitner's comment was so prejudicial that it could

not be cured by the Court's immediate instruction to the jury to disregard the comment or the jury instruction about Defendant's Fifth Amendment right not to testify. (Id.)

The Due Process Clause of the Fifth Amendment prohibits a prosecutor from commenting on the defendant's decision not to testify. See Griffin v. California, 380 U.S. 609, 615 (1965). A direct comment about the defendant's failure to testify always violates Griffin; a prosecutor's indirect comment violates Griffin "'if it is manifestly intended to call attention to the defendant's failure to testify or is of such a character that the jury would naturally and necessarily take it to be a comment on the failure to testify.'" Hovey v. Ayers, 458 F.3d 892, 912 (9th Cir. 2006) (quoting Lincoln v. Sunn, 808 F.2d at 809).

In Hovey, the Ninth Circuit found a prosecutor's indirect comment that the defendant never explained his actions to the jury or contradicted testimony of other witnesses violated Griffin. 458 F.3d at 912. The Ninth Circuit found the error harmless, however because it was an isolated comment, the government did not stress to the jury an inference of guilt from the defendant's silence, and there was sufficient evidence to support the defendant's conviction. Id.

Here, Agent Leitner mentioned Defendant's ability to explain what he said during Defendant's interview with Agent Leitner; thus, the statement constituted, at most, an indirect reference to Defendant's choice not to testify at trial, i.e., Defendant chose not to explain his "I'm not a man" statement to the jury. Even if this violated Griffin, under Hovey, any error was harmless: (1) this was a single comment with an immediate, sustained objection, and a curative instruction to the jury with no further mention of or reference to the statement; (2) the Government did not stress any inference of guilt from Defendant's decision not to testify; and (3) there was sufficient evidence to support the conviction, as discussed in detail below.

Furthermore, Defendant's argument is not persuasive for an additional reason. In the case law described above and relied upon by Defendant, the improper comment or argument was made by the prosecutor; here, the comment was made by a government witness, a federal law enforcement officer, but not the attorney for the Government.

Accordingly, the Court finds Agent Leitner's comment not a sufficient basis upon which to grant the Motion for New Trial.

Defendant argues an additional basis for his Motion for New Trial, that the Government failed to present any evidence to support the essential elements of the misbranding offense which necessitates a new trial on the smuggling counts. The Court discusses this basis below, in Section III(B)(3).

III. MOTION FOR JUDGMENT OF ACQUITTAL

Defendant Dr. Patwardhan cites the following grounds for his Motion for Acquittal: (1) "the government introduced no evidence of a nexus between the introduction into interstate commerce of foreign medicines and the alleged misbranding violations"; and (2) "the government never introduced evidence establishing the requisite nexus between the alleged fraud and the alleged misbranding violations" or "evidence of materiality." (See Mot. at 18-25.)

A. Legal Standard

Rule 29(c) of the Federal Rules of Criminal Procedure ("Rule 29(c)") permits a defendant to move for a judgment of acquittal after a guilty verdict if the evidence adduced at trial was insufficient to sustain a conviction. "'There is sufficient evidence to support a conviction if, viewing the evidence in the light most favorable to the prosecution, any rational trier of fact could have found the essential elements of the offense[]

charged beyond a reasonable doubt.' In conducting this review, '[the Court is] powerless to question a jury's assessment of witnesses' credibility,' and 'must presume ... that the trier of fact resolved any ... conflict[ing inferences] in favor of the prosecution.'" United States v. Johnson, 229 F.3d 891, 893 (9th Cir. 2000) (citing United States v. Hinton, 222 F.3d 664, 669 (9th Cir. 2000); see also United States v. Croft, 124 F.3d 1109, 1125 (9th Cir. 1997).

B. Discussion

1. United States v. Evers

Defendant argues the Government failed to prove all elements of the misbranding charges. In support of this basis for the Motion for Judgment of Acquittal, Defendant relies entirely on a Fifth Circuit case, United States v. Evers, 643 F.2d 1043 (5th Cir. 1981).

In Evers, the Fifth Circuit held the doctor-defendant did not misbrand the medicines he administered to his patients for a non-FDA-approved use because he did not distribute the drugs to other doctors. (See Mot. at 18-19.) According to Defendant, Evers stands for the principle that the Government could not prove his guilt of the misbranding Counts because he did not distribute the prescription drugs he imported to other physicians. (See Mot. at 18-20.)

The Court declines to apply the holding of Evers here for several reasons.

First, in Evers, the defendant was not charged under the same sections of the Food, Drug and Cosmetic Act ("FD&C Act") as the sections under which Defendant Patwardhan was charged. In seeking to enjoin Dr. Evers' practice of misbranding prescription drugs, the government argued Dr. Evers had violated Title 21 of the United States Code, Sections 331(k)[3] ("Section 331(k)") and 352(f)(1)[4] ("Section 352(f)(1)"). Id. at 1046. Here, the grand jury charged Dr. Patwardhan with violating Title 21 of the United States Code, Sections 331(a)[5] ("Section 331(a)"), 333(a)(2)[6] ("Section 333(a)(2)"), 352(c)[7] ("Section 352(c)"), and 352(f)(1).

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[3] This section states the following act is prohibited under the FD&C Act: "(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded."

[4] This section requires a label or labeling to include "(1) adequate directions for use."

[5] This section of the FD&C Act prohibits: "The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

[6] This section of the FD&C Act provides the penalties for violations of the Act.

[7] This section of the FD&C Act states a drug or

(continued...)

(See Second Superseding Indictment.) The only common alleged violation by Dr. Evers and Defendant Patwardhan was Section 352(f)(1).

Assuming, arguendo, Evers applies to Section 352(f)(1), mandating the Government prove the doctor-defendant distributed prescription drugs to other doctors to be found guilty, Evers does not require acquittal here. As the Government argues in Opposition, the Second Superseding Indictment gave two alternative bases for Dr. Patwardhan's misbranding conviction: (1) violation of 352(f)(1) because the labeling on the drugs he imported lacked adequate directions for use; and (2) violation of 352(c) because the "label or labeling was not in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[8] (Second Superseding Indictment at 14; Opp'n at 11-12, n.5) Although the Government did not prove Dr. Patwardhan distributed the drugs to other

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[7](...continued)
device is misbranded if: "(c) Prominence of information on label. If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."

[8] The Verdict Form for Counts Two and Three did not require the jury to select which basis it chose to establish Defendant's guilt.

doctors, the jury's conviction of Dr. Patwardhan on these Counts remains supported; pursuant to Section 352(c), the jury could have found Dr. Patwardhan guilty because the jurors found the label or labeling on the drugs Dr. Patwardhan imported and administered to his patients was not "in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 21 U.S.C. § 352(c).

Defendant argues Evers should be applied to Section 352(c) because "by law only physicians (or those acting under their supervision) can use prescription drugs, and thus any statutory duty imposed by Section 352(c) to have labeling that is comprehensible under 'customary conditions of purchase and use' is owed to physicians alone and can only be violated by distribution or intended distribution to physicians." (Reply at 13.)

Such an interpretation ignores the plain language of the statute, which uses the term "ordinary individual," not "ordinary physician." See Boise Cascade Corp. v. U.S. E.P.A., 942 F.2d 1427, 1432 (9th Cir. 1991) ("Under accepted canons of statutory interpretation, we must interpret statutes as a whole, giving effect to each word and making every effort not to interpret a provision in a manner that renders other provisions of the same statute inconsistent, meaningless, or superfluous."). Section

352(c) establishes a requirement that label or labeling on prescription drugs must be comprehensible by ordinary persons, including but not limited to doctors, when they purchase and use the products. See Avendano-Ramirez v. Ashcroft, 365 F.3d 813, 816 (9th Cir. 2004) ("Canons of statutory construction dictate that if the language of a statute is clear, we look no further than that language in determining the statute's meaning.")

Lastly, the factual distinctions between Evers and this case are many. The government charged Evers with advertising treatment for a certain medical condition with FDA-approved drugs but a non-FDA approved use; the Fifth Circuit held the government had not proven its case because it had not shown Dr. Evers distributed the drugs to other doctors, but only distributed and administered the drugs to his patients. Evers, 643 F.2d at 1053.

Here, of course, the Government charged Defendant with distributing non-FDA approved drugs; the evidence at trial established he distributed such medicines to his patients, and then charged them and their insurance carriers for the FDA-approved version.

Also, Evers obtained the FDA-approved drugs through ordinary distribution chains from pharmaceutical manufacturers, whereas Dr. Patwardhan introduced the non-

FDA-approved drugs into interstate commerce by importing them into the country himself or through his staff. Id. at 1049-50. Lastly, unlike Dr. Evers, Dr. Patwardhan was not advocating to other doctors a new treatment about non-approved uses for FDA-approved drugs; rather, Dr. Patwardhan administered non-FDA-approved drugs to his patients without their knowledge and profited from the venture. Id. at 1053, n. 16.

2. Dr. Patwardhan's Intent to Defraud or Mislead

Next, Defendant argues there was insufficient evidence of his purported intent to defraud or mislead to sustain his conviction for misbranding. (Mot. at 20-24.) Specifically, he argues the Government failed to prove a nexus between the particular misbranding violations and Defendant's purported intent to defraud or show that his misrepresentations were material. (Id. (citing United States v. Geborde, 278 F.3d 926, 930 (9th Cir. 2002); United States v. Arlen, 947 F.2d 139, 143 (5th Cir. 1991); United States v. Mitcheltree, 940 F.2d 1329, 1349-50 (10th Cir. 1991).)

Assuming, arguendo, the Government was required to prove Defendant specifically intended to defraud or mislead his patients as to adequacy of directions for use of the drugs or as to the comprehensibility of the labels or labeling on the drugs, the Government met its burden

of proof. See Mitcheltree, 940 F.2d at 1349-50. During trial, Kathy Walton testified that she contacted Defendant's office to inquire as to the name of one of the drugs she obtained for her mother's treatment because she did not recognize it. Defendant's employees testified that, following Ms. Walton's inquiry, Defendant was upset and restricted his employees from sending prescription drugs home with his patients, for fear they would ask more questions. This was evidence of Defendant's intent to mislead his patients as to the comprehensibility of the label or labeling of the drugs he administered to them, plus proof that his intent to defraud or mislead was connected directly to the comprehensibility of the label or labeling on the drugs. In addition, Ms. Walton's testimony showed her reliance on the comprehensibility of the labeling on her mother's prescription drugs that she obtained from Defendant.[9] See United States v. Nguyen, 565 F.3d 668 (9th Cir. 2009) (materiality is an undisputed element of felony misbranding); United States v. Watkins, 278 F.3d 961, 969 (9th Cir. 2002) (same).

Furthermore, as the Government argues, there was evidence at trial that Defendant and "his co-conspirators

[9] Defense counsel pointed out at the hearing that Defendant was not charged with misbranding the drug given to Kathy Walton's mother. Defense counsel was correct; this evidence, however, remains relevant to the issue of Defendant's intent to defraud or mislead.

made extensive efforts to avoid detection, including hiding drugs from auditors, misleading patients about where the drugs came from, [after the Kathy Walton incident] refusing to send the drugs home with patients for fear that the patients would start asking question, and lying to Medicare about the drugs." (Opp'n at 16.) Taken together, that evidence showed Defendant's specific intent to defraud or mislead his patients as to the comprehensibility of the label or labeling on the drugs and as to adequacy of the directions for use on the drugs.

Additional evidence of Defendant's intent to defraud and mislead was as follows: (1) Defendant never declared the drugs on his Customs forms; (2) Defendant lied to a Customs inspector about how long he had been traveling in India; (3) Defendant directed Velma Yep, a co-conspirator, to give drugs she purchased abroad at his direction to Jessica Young, another co-conspirator, and "no one else;" (4) Defendant asked Jessica Young to ask a doctor friend to buy drugs in India and not to mention that Defendant asked her to do so; (5) Defendant picked up the drugs personally instead of using an international courier; (6) the drugs were no longer cold when Defendant's staff inventoried them at the office; and (7) Defendant is an educated medical doctor who is familiar

with the FDA, its regulation of drugs, and its regulatory standards. (See Opp'n at 21-22.)

Contrary to Defendant's arguments, the Government presented sufficient evidence to support the conviction on the misbranding Counts. Viewing the evidence in the light most favorable to the Government, the Court finds a rational trier of fact would have convicted Defendant Dr. Patwardhan of the misbranding Counts; the Court DENIES the Motion for Judgment of Acquittal on the misbranding Counts.

3. Motion for New Trial on Smuggling Counts

According to Defendant, because the Government could not prove his guilt of the misbranding Counts, the Court should also grant him a new trial on the smuggling Counts because the jury may have found him guilty of the smuggling Counts improperly, based on the misbranding Counts. (Mot. at 26.) As the Court has found sufficient evidence supports Defendant's conviction on the misbranding Counts, the Court finds the conviction on the smuggling Counts has not been undermined. (Cf. Mot. at 18-20.) Thus, this argument is also insufficient to support Defendant's Motion for New Trial.

IV. CONCLUSION

Defendant fails to satisfy the burden imposed on the party seeking a new trial or acquittal, i.e., to show that the evidence preponderates heavily against the verdict. For the foregoing reasons, the Court DENIES Defendant's Motion for Judgment of Acquittal and/or New Trial.

Dated: July 18, 2009

VIRGINIA A. PHILLIPS
United States District Judge